Treatment of Tinnitus

Policy # 00127
Original Effective Date: 09/18/2002
Current Effective Date: 05/08/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Cochlear Implant is addressed separately in medical policy 00017.

Note: Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders is addressed separately in medical policy 00121.

Note: Auditory Brainstem Implant is addressed separately in medical policy 00475.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member’s contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider psychological coping therapy including cognitive-behavioral therapy, self-help cognitive-behavioral therapy, tinnitus coping therapy, acceptance and commitment therapy, and psychophysiological treatment, for persistent and bothersome tinnitus, when self-help or internet-based coping therapies were ineffective, to be eligible for coverage,**

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers treatment of tinnitus with ANY of the following therapies to be investigational*:

- Biofeedback; OR
- Tinnitus maskers, customized sound therapy; OR
- Combined psychological and sound therapy (eg, tinnitus retraining therapy) ; OR

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- Transcranial magnetic stimulation; OR
- Transcranial direct current stimulation; OR
- Electrical transcutaneous electrical stimulation of the ear, electromagnetic energy; OR
- Transmeatal laser irradiation.

Note: This policy does not address surgical (eg, cochlear or brainstem implant), pharmacologic treatment of tinnitus, (e.g., the use of amitriptyline or other tricyclic antidepressants), or injection of botulinum toxin.

**Background/Overview**

**Tinnitus**

Tinnitus describes the perception of any sound in the ear in the absence of an external stimulus and presents as a malfunction in the processing of auditory signals. A hearing impairment, often noise-induced or related to aging, is commonly associated with tinnitus. Clinically, tinnitus is subdivided into subjective and objective types. The latter describes the minority of cases, in which an external stimulus is potentially heard by an observer (eg, by placing a stethoscope over the patient’s external ear). Common causes of objective tinnitus include middle ear and skull-based tumors, vascular abnormalities, and metabolic derangements. The more common type is subjective tinnitus, which is frequently self-limited. In a small subset of patients with subjective tinnitus, its intensity and persistence lead to disruption of daily life. While many patients habituate to tinnitus, others may seek medical care if the tinnitus becomes too disruptive.

Many treatments are supportive because currently, there is no cure. One treatment, called tinnitus masking therapy, has focused on the use of devices worn in the ear that produce a broad band of continuous external noise that drowns out or masks the tinnitus. Psychological therapies may also be provided to improve coping skills, typically requiring 4 to 6 one-hour visits over an 18-month period. Tinnitus retraining therapy, also referred to as tinnitus habituation therapy, is based on the theories of Jastreboff, who proposed that tinnitus itself is related to the normal background electrical activity in auditory nerve cells, but the key factor in some patients’ unpleasant response to the noise is due to a spreading of the signal and an abnormal conditioned reflex in the extra-auditory limbic and autonomic nervous systems. The goal of tinnitus retraining therapy is to habituate (retrain) the subcortical and cortical response to the auditory neural activity. In contrast to tinnitus masking, the auditory stimulus is not intended to drown out or mask the tinnitus but is set at a level such that the
tinnitus can still be detected. This strategy is thought to enhance the extinction of the subconsciously conditioned reflexes connecting the auditory system with the limbic and autonomic nervous systems by increasing neuronal activity within the auditory system. Treatment may also include the use of hearing aids to increase external auditory stimulation. The Heidelberg model uses an intensive program of active and receptive music therapy, relaxation with habituation to the tinnitus sound, and stress mapping with a therapist.

Sound therapy is a treatment approach based on evidence of auditory cortex reorganization (cortical remapping) with tinnitus, hearing loss, and sound/frequency training. One type of sound therapy uses an ear-worn device (Neuromonics Tinnitus Treatment) prerecorded with selected relaxation audio and other sounds spectrally adapted to the individual patient’s hearing thresholds. This is achieved by boosting the amplitude of those frequencies at which an audiogram has shown the patient to have a reduced hearing threshold. Also being evaluated is auditory tone discrimination training at or around the tinnitus frequency. Another type of sound therapy being investigated uses music with the frequency of the tinnitus removed (notched music) to promote the reorganization of sound processing in the auditory cortex. One theory behind the notched music is that tinnitus is triggered by injury to the inner ear hair cell population, resulting in both a loss of excitatory stimulation of the represented auditory cortex and loss of inhibition on the adjoining frequency areas. It is proposed that this loss of inhibition leads to hyperactivity and overrepresentation at the edge of the damaged frequency areas and that removing the frequencies overrepresented at the audiometric edge will result in the reorganization of the brain.

Electrical stimulation to the external ear has also been investigated and is based on the observation that electrical stimulation of the cochlea associated with a cochlear implant may be associated with a reduction in tinnitus. Transcranial magnetic stimulation, electrical stimulation, and transmeatal low-power laser irradiation have also been evaluated.

**FDA or Other Governmental Regulatory Approval**

**U.S. Food and Drug Administration (FDA)**
The Neuromonics® Tinnitus Treatment is one of many tinnitus maskers cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. It is “…intended to provide relief from the disturbance of tinnitus while using the system, and with regular use (over several months) may provide relief to the patient whilst not using the system.”
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FDA product code: K LW.

### Table 1. Devices Cleared by the U.S. Food and Drug Administration

<table>
<thead>
<tr>
<th>Devices</th>
<th>Manufacturer</th>
<th>Date Cleared</th>
<th>510(k) No.</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiflex Tinnitus Technology</td>
<td>Starkey Laboratories</td>
<td>6/19/2020</td>
<td>K201370</td>
<td>Tinnitus Relief</td>
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<tr>
<td>Tinnitus Sound Generator Module</td>
<td>Gn Hearing A/S</td>
<td>2/20/2020</td>
<td>K193303</td>
<td>Tinnitus Relief</td>
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<tr>
<td>Tinnitus Sound Generator Module</td>
<td>Gn Hearing A/S</td>
<td>11/30/2018</td>
<td>K180495</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Audifon Tinnitus-Module</td>
<td>Audiofon Usa Inc.</td>
<td>10/19/2017</td>
<td>K171243</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Tinnilogic Mobile Tinnitus Management De</td>
<td>Jiangsu Betterlife Medical Co., Ltd.</td>
<td>5/17/2017</td>
<td>K163094</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Sound Options Tinnitus Treatment</td>
<td>Sound Options Tinnitus Treatments Inc.</td>
<td>9/28/2016</td>
<td>K161562</td>
<td>Tinnitus Relief</td>
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<tr>
<td>Hypersound Tinnitus Module</td>
<td>Turtle Beach Corporation</td>
<td>8/23/2016</td>
<td>K161331</td>
<td>Tinnitus Relief</td>
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<tr>
<td>Desyncra For Tinnitus Therapy System, De</td>
<td>Neurotherapies Reset Gmbh.</td>
<td>1/20/2016</td>
<td>K151558</td>
<td>Tinnitus Relief</td>
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<tr>
<td>Reve134</td>
<td>Kw Ear Lab, Inc</td>
<td>10/9/2015</td>
<td>K151719</td>
<td>Tinnitus Relief</td>
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</table>
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<table>
<thead>
<tr>
<th>Product Name</th>
<th>Manufacturer</th>
<th>Date</th>
<th>Code</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serenity</td>
<td>Sanuthera, Inc.</td>
<td>7/27/2015</td>
<td>K150014</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Soundcure Serenade Tinnitus Treatment Sy</td>
<td>Soundcure, Inc.</td>
<td>4/13/2015</td>
<td>K150065</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Levo Tinnitus Masking Software Device</td>
<td>Otoharmonics Corp</td>
<td>7/18/2014</td>
<td>K140845</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Solace Sound Generators</td>
<td>Amplisound Hearing Products &amp; Services</td>
<td>3/25/2014</td>
<td>K132965</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Tinnitus Sound support</td>
<td>Oticon A/S</td>
<td>3/18/2014</td>
<td>K133308</td>
<td>Tinnitus Relief</td>
</tr>
<tr>
<td>Wave 2g, Soul</td>
<td>Hansaton Akustik Gmbh</td>
<td>1/3/2014</td>
<td>K130937</td>
<td>Tinnitus Relief</td>
</tr>
</tbody>
</table>

**Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Various nonpharmacologic treatments are being evaluated to improve the symptoms of tinnitus. These approaches include psychological coping therapies, sound therapies, combined psychological and sound therapies, repetitive transcranial magnetic stimulation, electrical and electromagnetic stimulation, and transmeatal laser irradiation.

**Summary of Evidence**

For individuals who have persistent, bothersome tinnitus who receive psychological coping therapy, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant
outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. These therapies are intended to reduce tinnitus impairment and improve health-related quality of life. Meta-analyses of a variety of cognitive and behavioral therapies (CBTs) have found improvements in global tinnitus severity and quality of life, even when tinnitus loudness is not affected. Other RCTs have reported that a self-help/internet-based approach to CBT or acceptance and commitment therapy (ACT) may also improve coping skills. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have tinnitus who receive sound therapy, the evidence includes RCTs and a systematic review of RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on tinnitus masking includes RCTs and a systematic review of RCTs. The RCTs had medium- to high-risk of bias and did not show the efficacy of masking therapy. Research on customized sound therapy appears to be at an early stage. For example, the studies described the use of very different approaches for sound therapy, and it is not yet clear whether therapy is more effective when the training frequency is the same or adjacent to the tinnitus pitch. A 2016 trial, double-blind and adequately powered, found no benefit of notched music on the primary outcome measures of tinnitus perception and tinnitus distress, although the subcomponent score of tinnitus loudness was reported to be reduced. Two more recent RCTs evaluating notched music therapy for tinnitus found no significant differences in efficacy between this approach and ordinary music therapy or counseling. A benefit on tinnitus loudness, but not tinnitus perception or tinnitus distress is of uncertain clinical significance, may be spurious, and would need corroboration in additional studies. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

For individuals who have tinnitus who receive combined psychological and sound therapy, the evidence includes RCTs. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence on tinnitus retraining therapy consists of a number of small randomized or quasi-RCTs. Collectively, the literature does not show consistent improvements in the primary outcome measure (Tinnitus Handicap Inventory or Tinnitus Questionnaire scores) when tinnitus retraining therapy is compared with active or sham controls. For Heidelberg neuro-music therapy, a trial has used an investigator-blinded RCT design and showed positive short-term results following treatment. However, the durability of treatment is also unknown. A large, multicenter RCT trial using an intensive, multidisciplinary intervention showed improvement in outcomes. However, it is uncertain whether the multiple intensive interventions used in this trial
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could be replicated outside of the investigational setting. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

For individuals who have tinnitus who receive transcranial magnetic stimulation, the evidence includes a number of small- to moderate-sized RCTs and systematic reviews. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Results from these studies are mixed, with some trials reporting a statistically significant effect of repetitive transcranial magnetic stimulation on tinnitus severity and others reporting no significant difference. Larger controlled trials with longer follow-up are needed for this common condition. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

For individuals who have tinnitus who receive electrical or electromagnetic stimulation, the evidence includes a number of sham-controlled randomized trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence does not currently support the use of these stimulation therapies. A 2015 sham-controlled study that was adequately powered found no benefit of transcranial direct current stimulation (tDCS). Moreover, while a 2017 meta-analysis found some benefit for tDCS, it was noted that further study would be needed to evaluate tDCS as a treatment option. Studies have not shown a benefit for direct current electrical stimulation of the ear. The evidence on electromagnetic energy includes a small RCT, which found no benefit for the treatment of tinnitus. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

For individuals who have tinnitus who receive transmeatal laser irradiation, the evidence includes RCTs and crossover trials. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The evidence for transmeatal laser irradiation includes a number of double-blind RCTs, most of which showed no treatment efficacy. The evidence is insufficient to determine that the technology results in an improvement in the health outcome.

Supplemental Information
Practice Guidelines and Position Statements
Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given...
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to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Otolaryngology – Head and Neck Surgeons
In 2014, the American Academy of Otolaryngology - Head and Neck Surgeons published evidence-based guidelines on tinnitus. Table 2 provides some of the Academy’s recommendations.

Table 2. Guidelines on Treatment of Tinnitus

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>SOR</th>
<th>GOE</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Clinicians must differentiate patients with bothersome tinnitus from patients with nonbothersome tinnitus”</td>
<td>Strong recommendation</td>
<td>B</td>
</tr>
<tr>
<td>“Clinicians should distinguish patients with bothersome tinnitus of recent onset from those with persistent symptoms (≥ 6 months) to prioritize intervention and facilitate discussion about natural history and follow-up care”</td>
<td>Recommendation</td>
<td>B</td>
</tr>
<tr>
<td>“Clinicians may recommend sound therapy to patients with persistent, bothersome tinnitus”</td>
<td>Option</td>
<td>C</td>
</tr>
<tr>
<td>“Clinicians should recommend cognitive behavioral therapy to patients with persistent, bothersome tinnitus”</td>
<td>Recommendation</td>
<td>A</td>
</tr>
<tr>
<td>“Clinicians should not routinely recommend antidepressants, anticonvulsants, anxiolytics, or intratympanic medications for a primary indication of treating persistent, bothersome tinnitus”</td>
<td>Recommendation against</td>
<td>B</td>
</tr>
<tr>
<td>“Clinicians should not recommend transcranial magnetic stimulation for the routine treatment of patients with persistent, bothersome tinnitus”</td>
<td>Recommendation against</td>
<td></td>
</tr>
</tbody>
</table>

GOE: grade of evidence; SOR: strength of recommendation.

U.S. Preventive Services Task Force Recommendations
Not applicable.

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Medicare National Coverage
The Centers for Medicare & Medicaid Services had a longstanding national coverage determination for tinnitus masking, which was retired in 2014.

Ongoing and Unpublished Clinical Trials
Some ongoing trials that might influence this review are listed in Table 3.

Table 3. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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</thead>
<tbody>
<tr>
<td><strong>Ongoing</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT04551404</td>
<td>Transcranial Electrical and Acoustic Stimulation for Tinnitus: A Randomized Double Blind Clinical Trial</td>
<td>40</td>
<td>Dec 2024</td>
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<tr>
<td>NCT03754127</td>
<td>A Randomized Controlled HD-tDCS Trial: Effects on Tinnitus Severity and Cognition</td>
<td>81</td>
<td>Mar 2022</td>
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<tr>
<td>NCT03511807</td>
<td>Acoustic and Electrical Stimulation for the Treatment of Tinnitus</td>
<td>100</td>
<td>Jul 2022</td>
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<tr>
<td>NCT03544359</td>
<td>Longitudinal Functional MRI Study of Transcranial Electrical Stimulation in Chronic Tinnitus</td>
<td>35</td>
<td>Dec 2022</td>
</tr>
<tr>
<td>NCT04663828</td>
<td>UNification of Treatments and Interventions for Tinnitus Patients - Randomized Clinical Trial (UNITI-RCT)</td>
<td>500</td>
<td>Apr 2023</td>
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<tr>
<td>NCT04661995</td>
<td>Notched Noise Therapy for Suppression of Tinnitus: A Randomized Controlled Trial</td>
<td>108</td>
<td>May 2026</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

a Denotes industry-sponsored or co-sponsored trial.
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Policy History
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09/11/2002 Medical Director review
09/18/2002 Managed Care Advisory Council approval
10/05/2004 Medical Director review
11/16/2004 Medical Policy Committee review
  Format revision. Policy amended to include transmeatal irradiation as investigational.
11/29/2004 Managed Care Advisory Council approval.
07/07/2006 Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
11/01/2006 Medical Director review
11/15/2006 Medical Policy Committee approval. Coverage eligibility updated. Additional techniques in the treatment of tinnitus are also considered investigational: Electromagnetic energy, transcranial magnetic stimulation and Botulinum toxin A.
11/05/2008 Medical Director review
11/18/2008 Medical Policy Committee approval. No change to coverage.
11/12/2009 Medical Policy Committee approval
11/04/2010 Medical Policy Committee review
11/03/2011 Medical Policy Committee review
11/01/2012 Medical Policy Committee review
11/28/2012 Medical Policy Implementation Committee approval. No change to coverage.
11/07/2013 Medical Policy Committee review
11/20/2013 Medical Policy Implementation Committee approval. No change to coverage.
11/06/2014 Medical Policy Committee review
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08/03/2015 Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/29/2015 Medical Policy Committee review
11/16/2015 Medical Policy Implementation Committee approval. No change to coverage.
11/03/2016 Medical Policy Committee review
11/16/2016 Medical Policy Implementation Committee approval. Transcranial direct current stimulation added to investigational statement.
01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes
04/06/2017 Medical Policy Committee review
04/19/2017 Medical Policy Implementation Committee approval. Added coverage statement for psychological coping therapy for tinnitus and removed tinnitus retraining therapy, tinnitus coping therapy and botulinum toxin A injections from investigational statement.
04/05/2018 Medical Policy Committee review
04/18/2018 Medical Policy Implementation Committee approval. Biofeedback added to investigational list. Eligible for coverage statement changed to “Based on review of available data, the Company may consider psychological coping therapy including cognitive-behavioral therapy, self-help cognitive-behavioral therapy, tinnitus coping therapy, acceptance and commitment therapy, and psychophysiological treatment, for persistent and bothersome tinnitus, when self-help or internet-based coping therapies were ineffective, to be eligible for coverage.”
04/04/2019 Medical Policy Committee review
04/24/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/02/2020 Medical Policy Committee review
04/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/01/2021 Medical Policy Committee review
04/14/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/07/2022 Medical Policy Committee review
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04/13/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/06/2023 Medical Policy Committee review
04/12/2023 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 04/2024

Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>97014, 97026, 97032</td>
</tr>
<tr>
<td>HCPCS</td>
<td>C1816, C1883, E0720, E0761, S8948</td>
</tr>
</tbody>
</table>

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

1. Consultation with technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
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C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.